SUMMARY

I initiated this inspection of a manufacturer of a type 3 permanent implantable contraceptive device conducted in accordance with FACTS Assignment 8676539 as part of SAN-DO's FY '13 workplan for medical devices. I conducted this inspection pursuant to CP 7382.845 under PACs 82845A and 81011.

Previous inspection on Dec. 2010 to Jan 2011, covered Corrective and Preventive Actions (CAPA) and Management Controls. That inspection found that the firm was not reporting as MDRs complaints in which their product migrated from the fallopian tube into the peritoneal cavity, the firm did not consider these complaints in their risk analysis for the design of their product, and the firm failed to document CAPA activities for a supplier corrective action. That inspection was classified VAI.

Inspected firm:	Conceptus, Inc.
Location:	331 E Evelyn Ave Mountain View, CA 94041-1530
Phone:	650-962-4000
FAX:	(650)691-4729
Mailing address:	331 E Evelyn Ave Mountain View, CA 94041-1530
Dates of inspection:	5/30/2013, 5/31/2013, 6/3/2013, 6/4/2013, 6/5/2013, 6/6/2013, 6/7/2013, 6/10/2013, 6/11/2013, 6/12/2013, 6/13/2013, 6/17/2013, 6/25/2013, 6/26/2013
Days in the facility:	14
Participants:	Timothy C. Grome, Investigator

On May 22, 2013 I pre-announced the inspection to Henry V. Bishop, Quality Manager. On May 30, 2013, I showed my credentials to and issued an FDA 482 (Notice of Inspection) to D. Keith Grossmann, President & CEO. According to his admission and that of all of the firm officials present at the opening meeting was the most responsible person in charge at the start of the inspection.

During the current inspection Conceptus, Inc. was acquired by Bayer Healthcare Pharmaceutical Division. At the close of the inspection Mr. Grossmann was a consultant contracted by Bayer. The most senior management official on-site by the close of the inspection was Joseph G. Sharpe, Executive Vice President. This was by the admission of Mr. Sharpe, and Mr. Bishop. Also at the close of this inspection the firm was preparing to move their headquarters over the first week of July to the new address.

Joseph G. Sharpe, Executive Vice President
1101 McCarthy Blvd.
Milpitas, CA 95035

Current Inspection on July 9 to 11, 2008 covered CAPA and Design Controls, and reporting of MDRs.

I asked firm officials if Conceptus, Inc. has had any recalls or field corrections since January 2011. Henry V. Bishop, Quality Manager, told me that there have been no recalls or field corrections in the past two years.

I reviewed the firm's procedures for complaints:
Product Returns, Complaints Handling and Reporting SOP-1630 Rev. AE (7/29/11)
MDR Processing WI-03306 Rev. F (8/16/12)

I requested for a complete list of complaints since January 2011. Mr. Bishop provided me with a CD-ROM with an Excel file that contained 16,047 entries for complaints. He also provided me with a list of MDRs. I requested and reviewed 11 random complaint forms (Binomial Staged Sampling Plan, Confidence Limit 0.95 =< 0.25 ucl). I requested and reviewed an additional 18 complaint forms. The additional complaint forms that I reviewed contained the keywords, "peritoneal" or abdominal" cavity with "pain", or pregnancy. All of the complaints in which one or more coils were imaged outside of the fallopian tubes, had documentation that the patient was not -at last contact – experiencing pain. As such those complaints were not reported as MDRs.

The pregnancy complaints that I looked at were the ones in which the patient chose to continue the pregnancy. I asked Henry V. Bishop, Quality Manager, if the firm has data on the outcomes of pregnancies that had occurred after Essure placement. He said that there was no data compiled but had the firm compile data for me (Exhibit #1). This graph was compiled from 132 complaints between January 2011 and March 2013. Three of the categories are for the patient plan at time of last contact by Conceptus: "Plan for live birth", "plan for medical termination", and "undecided". Three other categories were for known outcome of the pregnancy: "Medical termination", "miscarriage", and "Live birth (healthy; uncomplicated)". I searched for "miscarriage" with "migration" of coil or "coil in uterus" and found no results.

I followed up on 3 FDA Consumer Complaints for Conceptus, Inc. These complaints were entered into the firm's data base from MAUDE. These complaints were assessed per the firm's complaint handling procedures.

I reviewed the firm's procedure for Corrective and Preventive Action, Corrective and Preventive Actions SOP-00935 Rev. U (9/22/10); I reviewed the list of all CAPAs since January 2011. From this list I selected 11 random CAPAs (Binomial Staged Sampling Plan, Confidence Limit 0.95 =< 0.25 ucl). Four of these CAPAs were the CAPAs opened in response to the observations of the previous inspection. The current inspection found no objectionable conditions with CAPA system.

Since the previous inspection Conceptus, Inc. has had no completed new full product designs. For design control review I chose the design for the(b) (4) (b) (4) This product is currently between (b) (4) stages. I reviewed the following design procedures: Product Development Process SOP-00799 Rev. V. I reviewed the design history file DHF(b) (4) initiated on(b) (4) The new design(b) (4) (b) (4) is a product of(b) (4) I reviewed customer needs, specifications, and (b) (4) tests. I also reviewed the Risk Management Plan(b) (4) (Exhibit #2).

Since the previous inspection the former Chief Executive Officer and President, Mark M. Sieczkerak was replaced with D. Keith Grossmann (Exhibit #3). By the close of the inspection Conceptus, Inc. was purchased by Bayer Healthcare Pharmaceutical Division, Mr. Grossmann was a consultant.

At the close out meeting on June 26, 2013, I discussed with firm management present the exclusion of risk assessment for safety of loose coils inside the peritoneal cavity in Risk Management Plan (b) (4) . This was one of the observations from the previous inspection. Henry V. Bishop, Quality Manager, told me that the FMEA does have perforation (Exhibit #2, pages 1 and 2) and expulsion (Exhibit #2, page 5). All of the observations from the previous inspection had been corrected. I warned firm officials present at the close-out meeting that no even though I was not issuing an FDA 483, that does not mean that there could be, at their firm, conditions which may be objectionable. I warned of penalties for violation of the Food, Drug, and Cosmetic Act.

EXHIBITS COLLECTED

1. Pregnancy Report Data
2. (b) (4) Design FMEA for (b) (4) (14 pages)
3. Organization Chart for Conceptus, Inc. Senior Management Team

ATTACHMENTS

1. FDA 482 (Notice of Inspection)

Timothy C. Grome, Investigator